

REMARKS

Claims 1, 3-46 and 51-67 are presented for the Examiner's review and consideration. In this response, claims 1, 3, 5, 9, 10, 14-15, 19, 23, 25-26, 30, 31 and 43 have been amended, claim 2 has been canceled. Claims 63-67 were deemed to be constructively elected in the instant Office Action, and were therein withdrawn. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Request to Remove Finality

Applicant acknowledges with appreciation the information provided in the Response to Arguments section of the instant Office Action. Applicant respectfully submits that the level of detail provided in this section would have been helpful in responding to the previous Office Action, wherein claimed elements were stated to be present in the prior art, but the rejection failed to provide sufficient supporting citations, references, reasoning or explanation.

As such, Applicant respectfully submits that the previous Rejection did not satisfy, at least, the requirements of MPEP §§707.07, 2142, and 2143.01(IV), and 37 C.F.R. §§1.104 and 1.113. More particularly, the Applicant was not provided with enough information in the previous Rejection in order to understand the Examiner's position.

In light of the foregoing, Applicant respectfully requests that Finality be removed.

Election / Restrictions

A restriction was required between Inventions (I): claims 1, 3-46, and 51-62; (II): claims 63-65, and 67; and (III): claim 66. A constructive election of Invention (I) was declared, and claims 63-67 were withdrawn. For reasons set forth below, Applicant respectfully submits that the restriction and constructive election were improper, and should be withdrawn.

The Restriction stated that Inventions I and II are unrelated. Applicant respectfully disagrees. Claim 63 contains all the elements of claim 1, reciting with further specificity how a patellar implant is engaged with a cut bone of the leg (patella). Claim 64 contains all of the elements of claim 1, but clarifies how the patella is maintained in a normal position (without subluxation), and how a bone of the leg is cut (using a guide wire). Claim 65 contains all the

elements of claim 1, including cutting bone (see e.g. Ref's. 1150/1152 of Fig. 75), and clarifies how the patella is maintained in a normal position (by hinging open the joint space). Claim 67 contains all the elements of claim 1, further clarifying how a bone is cut, and how the patella is maintained in a normal position. Accordingly, the claims are closely related, and claim 1 is usable with all of the restricted claims.

Applicant further respectfully submits that “non-everted” and “without a requirement of substantial subluxation” are not sufficiently different to support a reasonable interpretation of the claims as being “unrelated” with respect to a position of the patella.

Applicant additionally respectfully submits that Inventions (I) and (III) clearly overlap in scope. Claim 66 contains all of the elements of claim 1, and adds attaching a transducer and bladder, which relate to how the patella is maintained in a normal position.

In light of the foregoing, Applicant respectfully requests that the Requirement for Restriction and Constructive Election be withdrawn.

35 U.S.C. §103 Rejection

Claims 1, 4-12, 16-21, 24-25, 28-46, 51-52 and 57-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson et al. (U.S. Patent No. 5,683,469) (“Johnson”) in view of Waddell (U.S. Patent No. 6,174,314) (“Waddell”);

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell further in view of Howell (U.S. Patent No. 6,019,767) (“Howell”);

Claims 22-23, 54-56 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell further in view of Wang et al. (U.S. Patent No. 6,102,850) (“Wang”);

Claims 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell, further in view of Gustilo (U.S. Patent No. 5,733,292) (“Gustilo”);

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Waddell, further in view of Whitt (U.S. Patent No. 4,373,709) (“Whitt”);

Claims 1, 4-21, 24-25, 28-46, 51-52 and 57-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines (U.S. Patent No. 5,643,272) (“Haines”) in view of Waddell;

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Wang;

Claims 22-23, 54-56 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Wang;

Claims 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Gustilo. Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell, further in view of Gustilo; and,

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Haines in view of Waddell further in view of Whitt.

For reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

Initially, Applicant respectfully notes that the instant Office Action fails to provide adequate citations within the prior art for assertions of disclosures therein. This delays prosecution, and prejudices the Applicant. In addition, the Office Action does not meet the requirements of MPEP §§707.07, 2142, and 2143.01(IV), and 37 C.F.R. §§1.104 (particularly 1.104(c)(2)) and 1.113. Accordingly, Applicant respectfully submits that this represents an alternative basis for requesting removal of Finality. As such, Applicant respectfully requests either allowance be granted, or a replacement Office Action is provided with adequate supporting citations and explanations, and that Applicant is provided with a reasonable opportunity to amend the claims in response thereto.

Johnson and Haines

Discussions of Johnson and Haines were provided in a previous response, and in the interests of brevity, that discussion is incorporated by reference herein.

With respect to claim 21, the rejection states that Johnson and Haines each disclose “positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position”. No citations are provided within Johnson or Haines in support of this position. Applicant has carefully

reviewed the references, and respectfully submits that the references simply do not disclose the claimed subject matter.

The Remarks section of the Office Action states: “supporting the patient with the lower portion of the leg suspended from the upper portion of the leg (inherent, as the lower and upper knee portions are never completely severed from each other);”. Applicant respectfully submits that suspension is not inherent, in that it is tantamount to stating that a limb portion is suspended until it is severed. Suspended is defined as to “hang from somewhere” (AskOxford.com), or “to hang something from above, especially so that it can swing freely” (MSN Encarta). When a patient is in a prior art prone or supine position on an operating table, the lower leg is simply not hanging freely, and therefore cannot be deemed to be suspended. The instant invention discloses a suspended, or hanging limb, at least in paragraphs [0142], [0161], [0184], and [0205], and in Fig’s. 2-3, and 8-9. Accordingly, claim 21 is patentable over the cited references.

With respect to the remaining claims, the rejection admits that neither Johnson nor Haines disclose cutting the bone while the patella is not everted (i.e. with the inner side of the patella facing inward), reflecting a specific recitation in claim 1. It is assumed that this admission additionally includes the recitation in claims 16 and 19 of “the inner side of the patella faces towards a posterior portion of the knee portion of the leg”; the recitation in claim 31 of “the patella being disposed in a normal position relative to the knee portion of the leg”; and the recitation in claim 43 of “the patella remaining in a normal position relative to the knee portion”, as these particular recitations were not addressed in the rejection.

The Rejection further admits that neither Johnson nor Haines disclose “making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters”.

Waddell

A discussion of Waddell was provided in a previous response, and in the interests of brevity, that discussion is incorporated by reference herein.

Incision Size

The Rejection states that it although neither Johnson nor Waddell disclose an incision having a length between about seven and thirteen centimeters, it would have involved only routine skill in the art. Applicant respectfully disagrees.

Substantially reducing incision size is clearly not a matter of routine skill for at least the following reasons. Incision size directly correlates, at least, to the problems of disfigurement, tissue necrosis, prolonged recovery time, nerve damage, circulation damage, and opportunity for infection. Reducing incision size is therefore always a major motivation for any surgical procedure, and therefore it can be assumed that a known procedure is already using the shortest possible incision. Accordingly, a reduction in incision size may be presumed to involve a non-obvious change in the procedure, otherwise the improvement may be expected to already have been carried out.

The inventor has detailed the motivation for a reduced sized incision in an affidavit filed May 9, 2008, in U.S. Patent Application Serial No. 11/170,969. The relevant portion is repeated as follows:

“An incision of less than 13 cm offers a number of extremely important benefits not available prior to my invention. In particular:

a) Incisions in the skin of the knee necessarily involve cutting skin or cutaneous nerves, or denervating portions of the skin extending laterally to the incision, and thus there is a loss of sensation. This loss of sensation can cause simple movements, such as kneeling wearing clothes (pants), to be difficult to execute. In addition, affected areas of skin are not protected by nerve sensation, and being thus insensate, are vulnerable to damage, such as by puncture or burn, including burns by hot water [see Johnson DF, Love DT, Love BR, Lester DK, *Dermal Hypoesthesia after Total Knee Arthroplasty*, Am J Orthop, 2000 Nov; 29(11):863-6]. Traditional incisions for TKA surgery before the invention were typically in the range of 20 to 30 cm. A reduced size incision, particularly an incision of less than 13 cm, thus presents a substantially reduced potential for denervation, and an increased potential for better limb function.

b) Incisions in the skin of the knee necessarily involve cutting blood vessels, or devascularizing portions of the skin extending to either or both sides of the incision. Blood flow in the area of the incision is often reduced. A more serious problem arises in instances of revision surgery, where a subsequent operation in the same area is necessary. In this instance, a subsequent incision offset from the original incision can create an area of skin that potentially has a reduced or deficient blood supply. In this

instance, areas of skin can become necrotic, with attendant serious consequences. By creating a reduced size incision in the initial surgery, particularly an incision of less than 13 cm, there is greater opportunity to create a subsequent incision during revision surgery which does not bound an area of skin between the incisions, and thus the possibility for skin necrosis is greatly reduced.”

As Johnson, Haines, and Waddell do not disclose an incision size of 7 to 13 cm, and as there was significant motivation to do so, as outlined above, it cannot be said to be obvious. In contrast, the instant invention discloses performing a surgical procedure on the knee, through a smaller incision than suggested or taught in the prior art, while maintaining the patella in a normal position.

Waddell is chiefly concerned with forming patellar cuts which reflect the geometry of the patella in relation to installed trials. As the rejection indicates, Waddell does not address a reduced size incision (7-13cm). Thus, Waddell does not disclose displacing the patella from a normal position to an offset position with an inner side of the patella facing inward, through an incision having a length not more than 13 cm, as recited in claim 1. Claims 10, 16, 19, 23, 25-26, 30-31, and 43, as well as withdrawn claims 63-67, have similar recitations. The instant invention thus provides methods for cutting bone of the knee through a reduced size incision, which is not disclosed in the prior art.

Cutting Guide

While Waddell discloses a cutting guide, there is no disclosure in Waddell to indicate that the cutting guide therein is operable within a reduced sized incision.

Waddell discloses the guide is necessarily connected to a tibial or femoral trial: “Using an adapter base such as base 12 or 212, the guide 10 is mounted directly on a component of the total knee 30 system, such as the femoral or tibial trial.” (C6L28-30). “As shown in FIGS. 4-5, the resection guide is integrally mounted onto a femoral trial 320.” (C6L39-40).

Accordingly, in order to use the guide of Waddell in a reduced size incision, one must first implant a tibial and or femoral implant through a reduced size incision, and this is clearly not suggested or taught in Waddell. Accordingly, it can be concluded that the guide of Waddell

would not work through an incision size of 7-13cm, there not being the requisite supporting structure, and thus Waddell *does not disclose a patellar cutting guide usable through an incision size of 7-13cm.*

In contrast, claims 6, 7, 10, and 61, and withdrawn claim 67, provide a cutting guide usable with an incision size of 7-13 cm.

Accordingly, Applicant respectfully submits that claims 1, 10, 16, 19, 21, 23, 25, 26, 30, 31 and 43, and 63-67 are patentable over Johnson or Haines in view of Waddell. As claims 3-9, 13-15, 18, 22, 24, and 28-29 depend from Claim 1; 11-12 from 10; 17 from 16; 20 from 19; 27 from 26; 50, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62 from 30; 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42 from 31; and 44-46 from 43, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the section 103 rejections.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012B).

Respectfully submitted,

/ Gary S. Winer /

Gary S. Winer, Reg. #31,806 for
Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com